IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Gerhard SIEMEISTER et al. Examiner: HUGHES, Alicia R PhD

Serial No.: 10/796,174 Group Art Unit: 1614

Filed: MARCH 10, 2004 Confirmation No.: 3503

Title: **COMBINATIONS AND COMPOSITIONS WHICH INTERFERE WITH VEGF/ VEGF AND ANGIOPOIETIN/ TIE RECEPTOR FUNCTION AND THEIR USE (II)**

PETITION UNDER 37 CFR §1.144

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

It is respectfully requested that the Commissioner, through the honorable group Director, overturn the restriction requirement made final in the Office Action mailed June 10, 2008. The requirement for restriction was initially made FINAL in the Office Actions mailed November 2, 2006 and September 20, 2007 and following Applicants' submission with RCE of March 20, 2008, the finality of the restriction requirement was sustained in the Office Actions mailed June 10, 2008 and March 17, 2009.

Inasmuch as a Notice of Appeal to the FINAL Office Action of March 17, 2009 is being filed concurrently with this Petition, this paper is considered timely.

STATEMENT OF FACTS

The requirement for restriction mailed April 20, 2006, divides the application into three groups – Group I (claims 1-7 and 9-11), directed to a pharmaceutical composition comprising at least two specific compounds wherein compound I is a compound which modulates VEGF/VEGFR (or angiopoeitin/Tie2 receptor system, as set forth in claim 3) and compound II is a compound which modulates the angiopoeitin/Tie2 receptor system (or a compound targeted to the endothelium, as set forth in claim 2); Group II (claim 8), directed to a compound which can modulate both the VEGF/VEGFR system and angiopoeitin/Tie2 receptor system; and Group III

(claim 22), directed to a method of using a pharmaceutical composition for treatment of a disease/disorder. The restriction requirement further divided the claims of Groups I and II into two subgroups, each specifically directed to compounds which stimulated or inhibited the claimed systems.

The restriction requirement also set forth an election of species requirement. The Examiner required election of a single modulator species selected from:

i) a small molecular weight substance
ii) polynucleotides
iii) an oligonucleotide
iv) antisense oligonucleotide
v) an oligopeptide
vi) a recombinant protein
vii) an antibody
viii) a single chain antibody
ix) a conjugate or fusion protein of any one of the above

Furthermore, a nested species requirement was also set forth in the Office Action, wherein the Examiner required election of "**either 1 or 2** of the following compounds (emphasis added):" See page 6 of the Restriction Requirement mailed April 20, 2006.

a) any one (1) of SEQ ID NOS: 1-60 (claims 12 and 13)

b) (4-Chlorophenyl)[4-(4-pyridylmethyl)-phthalazin-1-yl]ammonium hydrogen succinate (or another specific small molecular weight molecule, which must be identified by name) (claims 15-18)

c) sTie2 (claims 14 and 17-21)

d) mAB 4301-42-35 (claims 14, 17-20)

e) scFv-tTF (claims 14, 17-21)

f) L19 scFv-tTF conjugate (claims 14, 17, 18)

In response to the requirement for restriction, Applicants elected with traverse Group I (claims 1–7 and 9-11) and further elected compounds **(b) and (c)** from the list of **small molecular weight substances** [subgroup (i)] that **inhibit or interfere with VEGF/VEGF** and/or receptor systems [Sub-group A] (emphasis added). See Applicants' response filed July 18, 2006.

The restriction requirement was initially made FINAL in the Office Action mailed November 2, 2006. The requirement for restriction has been continually traversed by Applicants.

New claim

Claim 24 was added in Applicants' response of March 20, 2008, to the Office Action mailed September 20, 2007 and is directed to pharmaceutical compositions comprising as compound I 4-Chlorophenyl)[4-(4-pyridylmethyl)-phthalazin-1-yl]ammonium hydrogen succinate and as compound II sTie2. Despite the fact that claim 24 explicitly reads on the elected species, it was held to be withdrawn in the Office Action mailed June 10, 2008.

New claim 23, which was presented in the aforementioned response, is directed to methods for treating a tumor or tumor metastasis in a subject comprising administering the compositions of the present application. Claim 23, like original claim 22, was held to be withdrawn due to being directed to non-elected inventions.

The restriction requirement, with respect to previously presented claims 14-18 and newly added claims 23 and 24 was again made FINAL in the non-final Office Action mailed June 10, 2008.

RELIEF REQUESTED

It is respectfully requested that:

1. Withdrawn claims 22–23 be rejoined for consideration and examination; and
2. The requirement for restriction be withdrawn, at least for claim 14-18 and 24.

Claims 14-18 and 24

Claims 14-18 and 24 have been incorrectly grouped with the withdrawn claims. No discussion of why these claims were withdrawn is found in the aforementioned Office Actions. It is respectfully submitted that claims 14-18 and 24 are directed to the elected invention, i.e., pharmaceutical composition(s) of the instant invention and moreover read on the elected species. See, page 5 of the Restriction Requirement mailed April 20, 2006 and Applicants' Reply filed July 18, 2006 and March 20, 2008. Claim 24 explicitly recites the elected species. It is not understood why the claims are directed to *non-elected subject matter*, as alleged in the Office Action. Favorable action is earnestly solicited.

Insofar as the PTO has agreed to examine the full scope of the genus claim(s), a search and examination of these claims would not pose undue burden on the Examiner. "If search and examination of an entire application can be made without serious burden, the examiner *must* examine it on the merits, even though it includes claims to independent or distinct invention." (Emphasis added). See, MPEP §803. Thus, these claims clearly should not be withdrawn. It is respectfully requested that the restriction requirement be overturned, at least, with respect to these claims.

Claim 22-23

The Examiner is urged to withdraw the restriction requirement/election, with respect to instant claims 22 and 23. Applicants submit that the subject matter of these claims are drawn to a method of using the compositions of claim 1 and recite all the elements of Applicants' composition claims. As noted previously, these are eligible for rejoinder upon allowance of generic product claims. See M.P.E.P. § 806.05.

Therefore, it is submitted that ample basis to overturn the requirement for restriction exists, and the same is respectfully requested.

No fees are believed to be due with this response; however, the Commissioner is hereby authorized to charge any additional fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

/Sagun KC/

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